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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,177	COME ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1636.

Applicant's election with traverse of Group IV (claims 28-42, 50-55, 63 and 65 in the reply filed on 12/17/2004 is acknowledged. Upon consideration of Applicant's arguments that Groups IV and V are closely related and share common features, the prior restriction requirement has been withdrawn. A new restriction requirement is presented below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 23-27 and 62, drawn to hybrid ligands and fusion polypeptides, classified in class 568, subclass 8, and class 530, subclass 350.

II. Claim 22 (as it reads on claim 16), drawn to a nucleic acid encoding a fusion polypeptide comprising segments P1, Cub-Z and RM, classified in class 536, subclass 23.1.

III. Claim 22 (as it reads on claim 17), drawn to a nucleic acid encoding a fusion polypeptide comprising P1 and Nux, classified in class 536, subclass 23.1.

IV. Claims 28-46, 48-55, 63 and 64, drawn to methods for identifying polypeptide sequences and a method of doing business comprising identifying polypeptide sequences, classified in class 435, subclass 6.

V. Claims 47 and 65, drawn to methods of identifying ligands, classified in class 435, subclass 7.1.

VI. Claims 56-58, drawn to a method of identifying a hybrid ligand suitable for an *in vivo* assay, classified in class 435, subclass 29.

VII. Claims 59-61, drawn to kits containing nucleic acids, classified in class 536, subclass 23.1.

NOTE: Claims 64 and 66 are improper multiple dependent claims. See MPEP § 608.01(n). Claim 64 has been included in Group IV because it depends from claims encompassed by this group. Claim 66 has not been placed in a group because it depends from claims of both Groups III and IV. Upon the election of Group III or Group IV, claim 66 will be included in the elected group.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the hybrid ligands of Group I may be used in a materially different process such as affinity chromatography.

The inventions of Groups IV-VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups IV-VI comprise steps which are not required for or present in the methods of the other group: providing a hybrid ligand having the general formula R1-Y-R2, where R2 is a user-specified ligand (Group

IV); providing a second chimeric hybrid ligand screening system comprising a second chimeric gene encoding a second fusion polypeptide comprising a user-specified ligand binding domain (Group V); and selecting a hybrid ligand with a particular linker that possesses suitable efficacy in inducing or allowing the detection of a detectable event (Group VI). The end results of the methods are different: identifying a polypeptide that binds to a user-specified ligand (Group IV); identifying a ligand that binds to a user-specified polypeptide (Group V); and identifying a linker of structure Y suitable for an *in vivo* assay in the context of a hybrid ligand of the general formula R1-Y-R2 (Group VI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The hybrid ligands of Group I, nucleic acids of Groups II and III, and kits comprising nucleic acids of Group VII are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). The nucleic acids of Groups II, III and VII are distinct from the nucleic acids do not encode the polypeptides of the same structure or function. Thus, the nucleic acids of Groups II and III are not part of the kits of Group VII. Therefore, the inventions of the groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups I-III and VII and Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I, II and VII are not necessarily used in or made by the methods of Groups IV-VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the search required for any one group is not required for any other group, and thus restriction for examination purposes as indicated is proper. Searching for any of the products will not necessarily identify the claimed methods. Further, each product requires a separate search of the patent and non-patent literature due to the different structural features of the hybrid ligand, or polynucleotide. Each nucleic acid sequence requires a separate search of the commercial sequence databases. The search for each method requires a separate search of the patent and non-patent literature to search the method step(s) not shared with any other group. Therefore, the searches are not coextensive, and the additional searching that is required to search more than one group would impose a serious search burden.

This application contains claims directed to the following patentably distinct species of the claimed invention: hybrid ligands and fusion polypeptides of **Group I** comprising combinations of the following sub-species types: \

1. R1 (e.g. one of claim 1(i)),
2. Y (e.g. one of claim 1(ii)),
3. R2 (e.g. one of claim 1(iii) or one of claim 14), and
4. fusion polypeptide (e.g. one of claim 23(ii)(a), 23(ii)(b), 24(ii)(a), or 24(ii)(b).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one of each sub-species type) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods for identifying polypeptide sequences that bind a user-specified ligand of **Group IV**, comprising the combinations of the following sub-species types:

1. R1 (e.g. one of claim 48(i)(a)),

2. Y (e.g. one of claim 48(i)(b)),

3. R2 (e.g. one of claim 1(i)(c) or one of claim 40), and

4. method step of detecting a detectable event (e.g. one of claim 28(iii-iv), or claim 43(iv)).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one of each sub-species type) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods of identifying a hybrid ligand suitable for an *in vivo* assay of **Group V**, comprising the combinations of the following sub-species types:

1. R1 (e.g. one of claim 58), and

2. Y (e.g. one of claim 57).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods for identifying polypeptide sequences that bind a user-specified ligand of **Group VI**, comprising the combinations of the following sub-species types:

1. R1 (e.g. one of claim 58), and

2. Y (e.g. one of claim 57).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one of each sub-species type) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business

Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

TERRY MCKELVEY
PRIMARY EXAMINER